

REMARKS/ARGUMENTS

This Amendment addresses the issues raised in the Official Action of September 3, 2008 and accompanies a Request for Continued Examination.

Amendments to the Claims

Claims 71, 86 and 94 have been amended. The basis for “intracellular delivery into tumor cells” added to claim 71 can be found in the specification in page 15, line 8; in addition, it is self evident that the delivery of camptothecin is to obtain an anticancer effect against tumor cells.

The basis for the provisos added to claims 71, 86 and 94 can be found in page 14 (where the compounds of Wang et al are disclosed only for gene delivery) and in the working examples (where these compounds are not tested). Claims 71, 86 and 94 use “consisting of” to define the liposomes.

Claim 75 has been amended to correct an obvious error since it now correctly refers to the compounds of formula (II) and not to camptothecins.

Claim 90 has been amended in order to clarify that it refers to the compounds of formula (II).

New claims 107-115 have been added. Support for claims 107, 110 and 113 can be found in page 36 lines 19-22. Support for claim 108, 111 and 114 can be found in page 37 lines 10-13. Support for claim 109, 112 and 115 can be found in page 37, lines 10-13, page 54 line 4 and page 5 line 6.

Response to Claim Rejections – 35 USC § 103

Wang et al in Combination with Allen, Burke, in Further Combination with Stracher

Examiner’s rejection will be further discussed by referring also to the previously presented remarks, which will not be repeated here, but still relied on.

The newly amended claims exclude the compounds of Wang et al, this limitation reflects the results of the working examples. In particular, in the working examples, the best mode of carrying out the invention is the liposome wherein the carnitine has C11/C16 alkyl/acyl chains. This compound is efficient in delivering CPT or taxol to tumor cells irrespective of the presence of a helper lipid.

This compound does not overlap with the compounds of Wang et al and demonstrates that, contrary to the compounds of Wang et al, the efficiency of delivery is irrespective of the

presence of an helper lipid and does not follow the rank alkyl/acyl chain C14 > C12 > C18/C18(9) > C16 > C18 for delivery efficiency.

In addition, the liposome of the present invention, as reflected by the “consisting of” terminology, does not include phospholipids since it is made only of the compounds of formula (II).

The above limitations make the present claims inventive over Wang et al *in combination with Allen, Burke, in further combination with Stracher.*

Hsu US5,653,996 in Combination with Wang

Applicants rely on the previously presented remarks and to the discussion made in the previous section.

The experimental results show that the entrapment of taxol or camptothecin within the liposome of the present invention leads to a better tropism of the anticancer agent toward the tumor site.

The skilled person in the field of oncology knows that targeting the anticancer agents toward the tumor site permits one to reduce/avoid the side effects of the anticancer drugs because the active agent can move toward the tumor site more efficiently and exert his cytotoxicity only in the tumor area.

The liposomes entrapping camptothecin can be targeted toward the tumor site in respect to camptothecin alone. The assays of pages 55-63 confirm this fact and particular attention is drawn to pages 55-58 and 62-63, Figure 3 of the drawings.

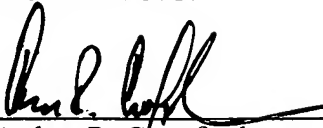
In view of the above, it is respectfully submitted the above claims are inventive over Hsu in combination with Wang et al. The applicant, respectfully, requests the reconsideration of the application and the withdrawal of the rejections.

PISANO et al
Appl. No. 10/624,645
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Respectfully submitted,

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